

**Remarks**

This Amendment is in response to the Office Action dated **March 11, 2009**.

***Rejections***

***35 U.S.C. §102(e)***

Claims 1, 6-9, 11, 12, and 17 have been rejected under 35 U.S.C. 102(e) as being anticipated by Zamore (U.S. Patent Application No. 2004/0093008).

Applicants traverse the rejection.

Independent claims 1 and 17 are directed to embodiments of a balloon having, body, waist portions and cone portions. The dilatation balloon is formed from a first polymeric composition that forms a first layer, the dilatation balloon further comprising a second layer that is crosslinked on at least the waist portions, cone portions, or both and the body portion of the balloon is uncrosslinked. Claim 1 further recites the crosslinked region is a compression region.

It is asserted in the Office Action that:

Zamore discloses a dilatation balloon with waist portions, cone portions, and a body portion where the balloon is formed of a first polymeric composition forming a first layer (A) and a second layer (B) is formed on at least a portion of the first layer. The second layer comprises a second polymeric composition which is crosslinked to form a compression region on at least a portion of the balloon. Zamore discloses that the second polymeric composition is crosslinked on at least a portion of the waist portions, the cone portions, or both (paragraph [0300]). Zamore also discloses that the body portion is uncrosslinked as shown in Figure 1B where the body portion of the first layer (A) is shown to be uncrosslinked.

Office Action, pp. 2-3

This is incorrect.

Zamore does not disclose that the second polymer composition is crosslinked on the waist portions, cone portions, or both, but not on the body portion.

Zamore describe in paragraph [0030]:

[0300] ... A co-extruded tube assembly T, consisting of an inner layer A comprising a thermoplastic polymer material that normally will not crosslink and an outer layer B is comprising a material compatible with layer A, but which is crosslinkable when exposed to crosslinking energy. The entire co-extruded tubing comprising crosslinkable layer B and non crosslinkable layer A, is then exposed to crosslinking energy. Only the portion of the tubing consisting of outer layer B will crosslink while the inner portion of the tubing consisting of layer A will remain uncrosslinked. Since Layer A remains uncrosslinked and therefore a thermoplastic, it will be weldable to another thermoplastic. The tubing consisting of crosslinked outer layer B, and thermoplastic inner B could be utilized to form a balloon in the previously described manner. A balloon with a crosslinked outer layer B and a thermoplastic inner layer A would result. The ends C of the formed balloon could thereafter be placed over the catheter shafts D and E and welded thereto. In summary, if the uncrosslinked, thermoplastic and weldable layer comprises the inner lumen of the ends of the formed balloon element (as shown in FIG. 1B) then a weldable tube could be placed with the lumen of the ends of the balloon and welded thereto. Alternatively, if the uncrosslinked, thermoplastic and weldable layer comprises the outer layer of the ends of the formed balloon element (not shown), then ends of the balloon element could be placed within the lumen of another fuse weldable tube and welded thereto. (emphasis added)

Clearly, the tubing is coextruded and the entire layer B is crosslinked. Nowhere does Zamore disclose or suggest that only the waist portions, cone portions or both are crosslinked while the body remains uncrosslinked.

In the Office Action, We are referred to FIG. 1B for the body portion being uncrosslinked. However, FIG. 1B is an illustration of the embodiment described in paragraph [0300] of Zamore. While step 3 of the process of forming the balloon illustrated by FIG. 4B shows layers A and B only on the waist portions of the balloon, Zamore is in fact disclosing for FIG. 1B, a balloon that is formed of a tubular member formed of two continuous extruded layers A and B, entire layer B which is then crosslinked. See steps 1 and 2 illustrated in FIG. 1B. Thus, Zamore is in fact disclosing a two layer balloon having one uncrosslinked layer A and one crosslinked layer B which is continuous with layer A. Applicants submit that the only reading of

FIG. 1B that is consistent with the specification description is that the cones and body of the balloon are formed of the same two material layers shown for the waists, but thinned by the balloon formation process. Please refer to paragraph [0300] and Example 7.

Therefore, claims 1 and 17 are not anticipated by Zamore. “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. §102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.” *Net MoneyIN Inc. v. VeriSign Inc.*, 88 USPQ2D 1751, 1758 (Fed. Cir. 2008) (cites omitted).

Claims 6-9, 11 and 12 depend from claim 1 and are not anticipated by Zamore for at least the reasons that claim 1 is not anticipated by Zamore.

Withdrawal of the rejection of claims 1, 6-9, 11, 12 and 17 under 35 U.S.C. §102(e) as being anticipated by Zamore is respectfully requested.

***35 U.S.C. §103(a)***

**Claims 1, 5-9, 11-13 and 17**

Claims 1, 5-9, 11-13, and 17 are rejected under 35 U.S.C. 103(a) as being obvious over Kaneko et al. (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008). It is asserted in the Office Action that:

Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the second layer being formed on at least a portion of the first layer and the second composition being selected from the group of olefins or comprising polyethylene (lines 47-53 of column 6), Kaneko et al. are silent on the specifics of the second polymeric composition being crosslinked to form a compression region and the body portion of the balloon being uncrosslinked. Zamore discloses a dilatation balloon with a first layer and a second layer on at least a portion of the

first layer where the second polymeric composition is crosslinked. Zamore also discloses that the body portion of the balloon is uncrosslinked as shown in Figure 1 B where the body portion of the first or inner layer (A) is shown to be uncrosslinked.

Applicants traverse the rejection.

As admitted in the Office Action, above, “Kaneko et al. are silent on the specifics of the second polymeric composition being crosslinked to form a compression region and the body portion of the balloon being uncrosslinked.”

As discussed above with respect to independent claims 1 and 17, Zamore does not disclose that the dilatation balloon is crosslinked on the waist portions, cone portions, or both, but not on the body portion.

Zamore disclose a tubular member wherein the layers are continuous with one another (see step 2 of FIG. 1B). The balloon is formed from this tubular member [0300].

As Kaneko et al. are silent as to the second polymer composition being crosslinked to form a compression region on the waist portions, cone portions, or both, and the body being uncrosslinked, and Zamore also fail to disclose or suggest these features, the combination fails to disclose or suggest all of the elements of claims 1 and 17 as required to establish *prima facie* obviousness under 35 U.S.C. §103(a).

“ ... [T]he prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

Applicants submit that because all of the features of claims 1 and 17 are not

disclosed or suggested by the combination of Kaneko et al. and Zamore, no *prima facie* showing of obviousness has been made.

Claims 5-9 and 11-13 depend from claim 1 and are not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claims 1, 5-9, 11-13, and 17 under 35 U.S.C. 103(a) as being obvious over Kaneko et al. (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008) is respectfully requested.

### **Claims 5 and 13**

Claims 5 and 13 have been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al.

It is asserted in the Office Action that “Zamore discloses the balloon substantially as claimed. However, Zamore is silent on a tie layer between the first layer and the second layer and a tie layer between the balloon and the catheter shaft. Kaneko et al disclose a tie layer (17) between a first layer (18) and the second layer (16) and a tie layer between the balloon and the catheter shaft.” Office Action, p. 6, no. 6.

Applicants traverse the rejection.

Claims 5 and 13 depend from claim 1.

Claim 1 has been discussed with respect to Zamore above. Zamore fails to disclose or suggest crosslinking of layer B on only the waist portions, cone portions, or both of the balloon.

Combining a tie layer such as disclosed by Kaneko et al. still fails to render claim 1 obvious because the combination still lacks the requisite disclosure of crosslinking a balloon only

on the waist portions, cone portions, or both, while leaving the balloon body uncrosslinked.

Zamore disclose crosslinking of the entire layer B.

Withdrawal of the rejection of claims 5 and 13 under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al. is respectfully requested.

**Claim 10**

Claim 10 has been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Smith et al. (U.S. Patent No. 6,083,587).

It is asserted in the Office Action that “Zamore discloses the balloon substantially as claimed. However, Zamore is silent on the specifics of a tie layer comprising polyethylene modified with at least one member. Smith et al disclose multilayered polymer structures for medical devices where a tie layer is formed between a first layer and a second layer.” Office Action, p. 6, no. 7.

Applicants traverse the rejection.

Claim 10 depends from claim 1.

Claim 1 has been discussed with respect to Zamore above. Zamore fails to disclose or suggest crosslinking of layer B on only the waist portions, cone portions, or both of the balloon while leaving the body portion of the balloon uncrosslinked.

Combining a tie layer comprising polyethylene modified with at least one member disclosed by Smith et al. as asserted in the Office Action, still fails to render claim 1 obvious because the combination still lacks the requisite disclosure of crosslinking a balloon only on the waist portions, cone portions, or both, while leaving the balloon body uncrosslinked.

Zamore disclose crosslinking of the entire layer B.

Withdrawal of the rejection of claim 10 under 35 U.S.C. §103(a) as being obvious over Zamore in view of Smith et al. is respectfully requested.

**Claim 10**

Claim 10 has been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al in view of Zamore as applied to claim 6 above, and further in view of Smith et al (U.S. Patent No. 6,083,587).

Applicants traverse the rejection.

Claim 10 depends from claim 1.

As discussed above, admittedly, Kaneko et al. does not disclose a balloon having a crosslinked layer on the waist portions, the cone portions or both, but the layer is not crosslinked on the body portion.

Zamore also fails to disclose or suggest crosslinking a layer only on the waist portions, the cone portions or both, but not on the body portion. Layer B disclosed by Zamore is coextruded with layer A (step two of FIG. 1B) and the entire layer is crosslinked (paragraph [0300]). Therefore, Zamore does not disclose crosslinking only a portion of the layer B as asserted in the Office Action.

No *prima facie* showing of obviousness has been made.

Withdrawal of the rejection of claim 10 as obvious over Kaneko et al. in view of Zamore is respectfully requested.

**Claims 14-16**

Claims 14-16 have been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al. as applied to claim 13 above, and further in view of Samuelson et al. (U.S. Patent No. 6,464,683). In the Office Action, Samuelson et al. is combined with Zamore and Kaneko et al. for the disclosure of a tie layer.

Applicants traverse the rejection.

Claims 14-16 depend from claim 1.

Claim 1 has been discussed with respect to Zamore and Kaneko et al., above. The combination of Zamore and Kaneko et al. fails to disclose or suggest crosslinking of one layer on only the waist portions, cone portions, or both of the balloon while leaving the body portion of the balloon uncrosslinked.

Combining a tie layer comprising polyethylene modified with at least one member disclosed by Smith et al. as asserted in the Office Action, still fails to render claim 1 obvious because the combination still lacks the requisite disclosure of crosslinking a balloon only on the waist portions, cone portions, or both, while leaving the balloon body uncrosslinked. Zamore disclose crosslinking of the entire layer B and Kaneko et al. fail to disclose or suggest crosslinking whatsoever.

Withdrawal of the rejection of claims 14-16 under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al. and further in view of Samuelson et al. is respectfully requested.



**Claims 14-16**

Claims 14-16 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al in view of Zamore as applied to claim 13 above, and further in view of Samuelson et al (U.S. Patent No. 6,464,683). In the Office Action, Samuelson et al. is combined for the disclosure of a tie layer.

Applicants traverse the rejection.

Claims 14-16 depend from claim 1.

Claim 1 has been discussed with respect to Kaneko et al. and Zamore, above. The combination of Zamore and Kaneko et al. fails to disclose or suggest crosslinking of one layer on only the waist portions, cone portions, or both of the balloon while leaving the body portion of the balloon uncrosslinked.

Combining a tie layer comprising polyethylene modified with at least one member disclosed by Smith et al. as asserted in the Office Action, still fails to render claim 1 obvious because the combination still lacks the requisite disclosure of crosslinking a balloon only on the waist portions, cone portions, or both, while leaving the balloon body uncrosslinked. Kaneko et al. fail to disclose or suggest crosslinking whatsoever and Zamore disclose crosslinking of the entire layer B, but not just the waist portions, cone portions or both of the balloon.

Withdrawal of the rejection of claims 14-16 under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Zamore and further in view of Samuelson et al. is respectfully requested.

**CONCLUSION**

Claims 1 and 5-17 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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